THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

NOV 19 2001

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE
CHAIRMAN OF THE JOINT CHIEFS OF STAFF

SUBJECT: Policy for the Use of Potassium Iodide for Protection of U.S. Personnel and Family Members

The use of stable iodine to protect the thyroid gland against uptake of inhaled and ingested radioactive iodine resulting from an accident at a nuclear power plant has long been recognized as an effective action by the World Health Organization, the U.S. Nuclear Regulatory Commission and the U.S. Food and Drug Administration (FDA). The U.S. military overseas, their families, U.S. civilian workers and contractors may be at risk from hostile actions and other events against nuclear power plants resulting in radioactive iodine release.

All Unified Commanders-in-Chief (CINCs) shall evaluate the threat of radioactive iodine release from nuclear power plants and risk of exposure to U.S. personnel in their areas of responsibility and develop their implementation plans on the use of potassium iodide (KI) in coordination with the Services. Services must ensure availability of supply of KI through normal logistics procedures. KI is an over-the-counter drug approved by the FDA for use in a radiation emergency to protect the thyroid gland from harmful radioactive iodine. Please provide the implementation plans to my point of contact by February 1, 2002.

It is noteworthy that draft guidelines recently issued by the FDA reduce the dosage recommendations for children by age group. KI dosage to different age groups, action levels and other guidance are suggested in these draft FDA guidelines (excerpt attached), available on the internet: http://www.fda.gov/cder/guidance/3698dft.pdf. Pending the final FDA guidelines (expected before the end of 2001), the dosage recommendations contained in the draft guidelines may be considered as part of the practice of medicine in the provider-patient relationship. This DoD policy will be reviewed when the FDA publishes the final guidance on KI use.

My point of contact is Colonel Robert Eng, Director of the Armed Forces Radiobiology Research Institute, at (301) 295-1210/0267 and email, eng@mx.afrri.usuhs.mil.

William Winkenwerder, Jr.

William Winkenwerder, Jr., MD

Attachment:
As stated

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Department of State

HA POLICY: 01-019

DRAFT
Food and Drug Administration Guidance
Potassium Iodide (KI) as a Thyroid
Blocking Agent in Radiation Emergencies (Dec 2000)

Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups				
	Predicted Thyroid exposure(cGy)	KI dose (mg)	# of 130 mg tablets	# of 65 mg tablets
Adults over 40 yrs	≥500	130	1	2
Adults over 18-40 yrs	≥10			
Pregnant or lactating women	≥ 5			
Adolesc. over 12-18 yrs*		65	1/2	1
Children over 3-12 yrs				
over 1 month-3 years		32	1/4	1/2
birth-1 month		16	1/8	1/4

* adolescents approaching adult size (≥ 70 kg) should receive the full adult dose (130 mg)

http://www.fda.gov/cder/guidance/3698dft.htm: 3 August 2001

1. Action Levels for KI administration to protect against thyroid cancer risk:

5 cGy or greater:	Children aged 0-18 years and pregnant or lactating women
10 cGy or greater:	Adults up to 40 years of age
500 cGy or greater:	Adults over 40 (to prevent hypothyroidism)

2. KI Dose Schedule

Age	Dosage
Adults over 40 yrs: Adults over 18 - 40 yrs Pregnant or lactating women	130 mg
Adolesc. Over 12-18 yrs Children over 3-12 yrs	65 mg
Over 1 month - 3 yrs	32 mg
Birth - 1 month	16 mg

3. For optimal protection against inhaled radioactive iodines, KI should be administered before or immediately coincident with passage of the radioactive plume, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. The protective effect of KI lasts approximately 24 hours. For optimal prophylaxis, KI should therefore be dosed daily, until a risk of significant exposure to radioactive iodines by either inhalation or ingestion no longer exists. Individuals intolerant of KI at protective doses and pregnant and lactating women (in whom repeat administration of KI raises particular safety issues) should be given priority with regard to other protective measures (i.e., sheltering, evacuation, and control of the food supply).

4. Note that sheltering with windows and doors closed and taped and ventilation to the outside turned off can provide significant protection to the occupants. Protective factors of 25 and greater are achievable.